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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/295,925      | 04/21/1999  | PHALGUN B. JOSHI     | 16303-007510        | 7753             |

20350 7590 05/21/2004

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

[REDACTED] EXAMINER

WOITACH, JOSEPH T

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER  
1632

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                   |                     |  |
|------------------------------|-------------------|---------------------|--|
| <b>Office Action Summary</b> | Application No.   | <b>Applicant(s)</b> |  |
|                              | 09/295,925        | JOSHI ET AL.        |  |
|                              | Examiner          | Art Unit            |  |
|                              | Joseph T. Woitach | 1632                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 20 February 2004.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-5,7-10,12 and 46 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1,7-10,12 and 46 is/are allowed.

6) Claim(s) 2-5 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This application filed April 21, 1999 claims benefit to provisional applications: 60/028,665, filed April 22, 1998; 60/111,653, filed December 9, 1998; and 60/111,637, filed December 9, 1998.

Applicants' after final amendment filed February 20, 2004 has been received and entered. Claim 1 has been amended. Claim 6, 11, 13-45 have been cancelled. Claims 1-5, 7-10, 12 and 46 are pending and currently under examination.

#### ***Election/Restriction***

Applicants' election made March 9, 2000, paper number 9, was made with traverse. Claims 13-45 drawn to the non-elected inventions have been cancelled. Pending claims 1-5, 7-10, 12 and 46 are drawn to the elected invention.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-10, 12 and 46 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

The amendment to claim 1 has obviated the basis of the rejection.

Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In particular, the courts have stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent

application. 27 USPQ2d 1662 *Ex parte Maizel*. It is well known in the art that radiation synchronizes mammalian cells at the G2 checkpoint (see for example Rieder *et al.* or Mikkelsen *et al.*). The specification does not provide the necessary teaching to change the inherent affect of radiation on cells, in particular in its affect on synchronizing cells. Since gamma rays, x-rays and ultraviolet rays all have the same affect on a given cell when administered under appropriate conditions and doses, and that affect is triggering cell cycle arrest at the G2 checkpoint, the present claims specifically encompassing cell cycle stages of S, G2/M boundary and when the nuclear membrane is degraded could not be practiced given the level of skill in the art and the guidance of the instant disclosure.

In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim is unclear in what is meant by the nucleic acid accumulates in cells that have cycled to the G2/M phase boundary because DNA is present throughout the cell cycle. Further, it is unclear how the claim differs from that set forth in claim 4 because each

result in cells synchronized at the G2/M phase boundary if one were to equate the accumulation of nucleic acid as an indication of synchronization.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 4.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Both claims 4 and 5 are dependent on claim 1, and though they are not identical and use different language, the metes and bounds of the claims are the same. In each case the resulting cell is synchronized as evidenced by the accumulation of nucleic acid in the G2/M phase boundary. Claim 5 indicates that the synchronized phase is something other than M phase which is broader than claim 4, however the claim continues indicating that "the nucleic acid accumulates in the cells" and that cells "have cycled to the G2/M phase boundary" which is simply a description of synchronization to the G2/M boundary encompassed by claim 4.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-9, 11, 12 and 46 rejected under 35 U.S.C. 103(a) as being unpatentable over Yorifuji *et al.* in view of Spang-Thomsen *et al.* is withdrawn.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yorifuji *et al.* in view of Spang-Thomsen *et al.* as applied to the claims above, and further in view of Son *et al.* is withdrawn.

The amendments to the claims and Applicants' arguments have been fully considered and have been found persuasive.

***Conclusion***

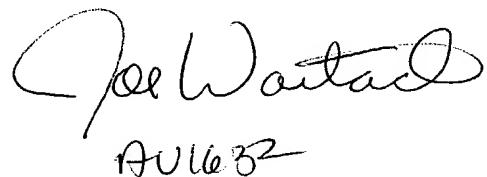
Claims 1, 7-10, 12 and 46 are allowed. The remaining claims are free of the art of record, however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



A handwritten signature in black ink, appearing to read "Joe Woitach". Below the signature, the date "AUG 6 32" is handwritten.